

US EPA ARCHIVE DOCUMENT

112701

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

12-17-85

MEMORANDUM

SUBJECT: Registrability of Brodifacoum the Anticoagulant

FROM: Daniel Rieder, Wildlife Biologist
Ecological Effects BranchTO: Mike Slimak, Chief
Ecological Effects Branch

On November 18, 1985, the terrestrial field study team met to discuss D. Rieder's review of ICI America's proposed field study protocol. See Field Study Protocol Review, attachment 2
Attending were:

Ken Clark
Ed Fite
Margaret Rotsker
Doug Urban
Zig Vaituzis
Dan Pieder

The team agreed that the review was accurate in that the proposed protocol was inadequate to provide the information necessary to negate EEB's concern for the use of Brodifacoum on orchards. The discussion then focused on what alternatives are available to EEB.

Background:

Brodifacoum is a second generation anticoagulant rodenticide. It is the active ingredient in Volid[®] rodenticide which is produced by ICI Americas, Inc. It is presently registered for control of rodents in and around urban buildings and in and around agricultural buildings. ICI proposes to register it for use in apple orchards. A field study was conducted in support of the "in and around agricultural buildings" use. See Abstract of "Evaluation of the Potential Hazard to Barn Owls of Talon Used to Control Rats and House Mice." Based on that study, it is apparent that barn owls never fed on rodents that had consumed Talon bait.

CONCURRENCES

SYMBOL	EEB/HEP	EEB/HEP	TS. 749				
SURNAME	Rieder	Fite	CWK				
DATE	12/16/85	12/17/85	12-17-85				

Some selected toxicity test results show that brodifacoum is very highly toxic to fish, birds and mammals.

<u>Species</u>	<u>T.M.</u>	<u>Test Type</u>	<u>Results</u>
Bluegill	92.5%	96-hr LC ₅₀	89 ppb measured
Rainbow trout	92.5%	96-hr LC ₅₀	45 ppb measured
<u>Daphnia magna</u>	93.3%	48-hr LC ₅₀	890 ppb nominal

The use rate and method of application precludes unreasonable adverse effects to aquatic organisms, however.

Primary Consumers

Mallard	Tech.	Acute Oral LD ₅₀	2 mg/kg 10% mort. at 0.3 mg/kg
Pheasant	**	Acute Oral LD ₅₀	10 mg/kg
Opposum	**	Acute Oral LD ₅₀	0.17 mg/kg
Rabbit	**	Acute Oral LD ₅₀	0.2 mg/kg 0.29 mg/kg
Mallard	94%	40-day LC ₅₀ (5-day feeding 35-day obs.)	2.7 ppm 30% mort. at 1 ppm
Bobwhite	94%	"	0.8 ppm* 80% mort. at 1.78 ppm 20% mort. at 1 ppm
Rat, albino	98%	5-day LC ₅₀ (19 days obs.)	0.57 ppm 1.0 ppm

* Raw mortality data were not provided in review, study shows 40-day LC₅₀ is probably between 1 ppm and 1.78 ppm.

** Assumed technical

Secondary Consumers

Beagle Dogs	Assumed tech.	LD ₅₀	> 0.25 < 1 mg/kg
Mink	?	LD ₅₀	9 mg/kg
Cats	Assumed tech.	"	approx. 25 mg/kg
American kestrel	?	LC ₅₀	6 ppm
Laughing gull	?	LC ₅₀	0.72 ppm

2

Secondary toxicity is a major problem when dealing with anticoagulants. Test data show that brodifacoum is persistent in the tissue (carcass) of rats with an estimated halflife of 150 to 200 days. This means that target and non-target rodents that feed on Volid pellets will provide a source of secondary toxicity long enough to have both acute and chronic effects to predators and scavengers.

Several secondary toxicity tests have been reviewed:

<u>Species</u>	<u>Test Description and Results</u>	<u>Comments</u>																					
Fox, red and gray	A total of 5 fox were tested. These fox were fed rats that had been killed by brodifacoum. 2 were fed 1 day, no mort. 1 was fed 3 days, 1 mort. 2 were fed 4 days, 1 mort. Surviving fox exhibited slight to moderate hemorrhaging as indicated by autopsy	The fox that did not die at 4 days had reduced its food consumption substantially compared to the one that died.																					
Barn owls	Six owls were fed with brodifacoum-killed rats.																						
	<table> <tr> <th><u>days fed</u></th><th><u>effect</u></th><th><u>Dose (mg)</u></th></tr> <tr> <td>1</td><td>none</td><td>0.58</td></tr> <tr> <td>3</td><td>death</td><td>2.5</td></tr> <tr> <td>3</td><td>"</td><td>1.75</td></tr> <tr> <td>6</td><td>"</td><td>3.84</td></tr> <tr> <td>10</td><td>"</td><td>3.15</td></tr> <tr> <td>10</td><td>"</td><td>3.30</td></tr> </table>	<u>days fed</u>	<u>effect</u>	<u>Dose (mg)</u>	1	none	0.58	3	death	2.5	3	"	1.75	6	"	3.84	10	"	3.15	10	"	3.30	
<u>days fed</u>	<u>effect</u>	<u>Dose (mg)</u>																					
1	none	0.58																					
3	death	2.5																					
3	"	1.75																					
6	"	3.84																					
10	"	3.15																					
10	"	3.30																					
Golden eagles, red-tailed hawks, red-shouldered hawks	4 eagles, 4 red-tails and 2 red-shouldered hawks were fed Norway rats killed with brodifacoum for 3 days																						
	<table> <tr> <th></th><th><u>mort.</u></th><th><u>observed effects</u></th></tr> <tr> <td>4 eagles:</td><td>0</td><td>3</td></tr> <tr> <td>4 red-tails:</td><td>4</td><td>4</td></tr> <tr> <td>2 red-should.:</td><td>1</td><td>2</td></tr> </table>		<u>mort.</u>	<u>observed effects</u>	4 eagles:	0	3	4 red-tails:	4	4	2 red-should.:	1	2										
	<u>mort.</u>	<u>observed effects</u>																					
4 eagles:	0	3																					
4 red-tails:	4	4																					
2 red-should.:	1	2																					
Kestrels	Twenty kestrels were fed with voles that had been killed with brodifacoum, 10 for 2 days, 10 for 6 days. None in the 2-day group died, 4 in the 6-day group died. Note: ViT. K was administered and is an antidote for anticoagulants.																						
Barn owl	Field study, see abstract, attachment 1.																						

A second field study was conducted by Hegdal, Colvin, Blaskiewicz and Schoenberg in fall 1981 and winter 1983. See the following abstract.

Abstract: During the fall and winter of 1981-1982, we conducted a radiotelemetry study on screech owls (Otus asio), barred owls (Strix varia), and 3 other raptorial species to evaluate the secondary hazards of the anticoagulant rodenticide, VOLID (10 ppm brodifacoum), when used for controlling voles (Microtus spp.) in orchards. Starting on 25 October 1981, we attached radio transmitters to 38 screech owls, 5 barred owls, 3 red-tailed hawks (Buteo jamaicensis), 2 great horned owls (Buteo virginianus), and 2 long-eared owls (Asio otus) and monitored their movements before, during, and after rodenticide treatment. Twenty-five screech owls were tracked in treated areas posttreatment. Secondary brodifacoum poisoning was stated as the probable cause of death of 6 screech owls based on radiotelemetry, necropsy, and residue data. Also, 1 long-eared owl (not radio-equipped) was apparently killed by secondary brodifacoum poisoning. We collected 6 radio-equipped screech owls about 2 months posttreatment and 4 contained brodifacoum residues at levels similar to those that died. The use of treated areas by barred owls was limited and none were found dead posttreatment. Data on the other radio-equipped raptors was insufficient to determine any potential secondary effects. In May 1982, we attempted to recapture all of the 18 radio-equipped screech owls that still could have been present in the area. Only 1 was recaptured. However, 8 additional screech owls, not previously encountered, were captured during this effort.

This study was validated by Russ Farringer in July and August 1983, as Invalid because more than one rodenticide was used in the home range of the owls during the study. While the abstract claims only 6 screech owls were killed by secondary toxicity effects of Volid, 4 screech owls were apparently victims of predation, 14 were not accounted for because of loss of contact. Any of these 20 owls (more than half the marked birds) may have been exposed to and adversely effected by Volid. No residue analysis is available on those 20 owls.

4

Furthermore, 4 of the 6 owls captured and sacrificed for residue analysis had high levels of brodifacoum in their livers. I believe that if a screech owl is weakened by a toxicant making him more susceptible to predation or other stresses that it is tantamount to the owl being killed by the toxicant. Therefore, this study suggests that from 6 to 30 screech owls were killed by brodifacoum. That translates to 15.7 percent to 79 percent. It would be very difficult for any future studies to show that the mortality observed and suspected in this study does not represent a substantial adverse effect to screech owl populations.

Three field studies were conducted in the U.K. The studies were designed to compare the efficacy and hazards to non-target species of various baiting methods and bait types. The two bait types were pelleted and block. The pellets were essentially coated wheat grains. The blocks were 20 g of treated grain packed together with wax. The results of carcass searches on 43 sites or farms where various amounts of bait were used were as follows.

Small birds	79
Corvids (jays, crows, magpies)	26
Rabbits	5
Cats	4
Grey squirrel	3
Tawny owl	2
Buzzard	2
Chicken	2
Pheasant	2
Fox	1
Stoat	1

These mortalities were attributed to Brodifacoum through post-mortem analysis. It was notable that when areas other than "around buildings" were treated, non-target mortality tended to be higher. These areas included fields, hedgerows and haystacks.

Summary

Brodifacoum is highly toxic to birds, mammals and fish. Both laboratory and field data have shown that Volid® poses a substantial secondary hazard to mammals and birds. The registrant hopes to show through further field studies that this adverse effect to individuals will not result in adverse population effects.

Conclusions

According to the field study group there are three alternatives in dealing with this situation.

1. Assist ICI in designing a field study that, hopefully, is adequate to measure adverse population effects to non-target bird and mammal species.

2. Retract the request for a full population field study and request that ICI perform several qualitative field studies looking for adverse effects to individuals of various bird and mammal species populations.

3. Retract the request for additional field work and use the available information to place Brodifacoum in special review.

The first option would likely involve contacting various field biologists and other experts outside the agency to determine what type of studies could and should be required and how they would be conducted. The outcome of these contacts would either be a field study protocol or a conclusion that it is not feasible for the registrant to perform such a study that could negate the presumed hazard.

The second option would reflect the fact that only one of the five field studies involved a use similar to the apple orchard use. The rest were with different, albeit less hazardous uses. This option would mean requiring the registrant to do several less expensive (relative to the first option type study) studies in various locations with several different bird and mammal species. It would likely involve the use of various techniques that measure effects to individual organisms rather than provide information on population effects.

I am least inclined to choose this option as it cannot, in my opinion, provide additional useful information. Even though some of the field studies were with different baiting techniques and use sites, they still show adverse effects to individual organisms from typical use of Brodifacoum. I believe further studies of this nature would be redundant.

I favor the third option. Four of the five field studies reviewed resulted in substantial non-target mortality. In the one that did not, it was shown that no exposure occurred to the test animal (Barn owls). It is unlikely that further field studies using similar baiting techniques would negate the existing hazard exhibited by earlier studies. Additional field work would not provide additional useful information other than, in my opinion, to strengthen our position that Brodifacoum is too hazardous to be registered for use as a field rodenticide. It is not so much that an adequate study or studies cannot be designed that would show safety. Rather, the magnitude of evidence against Brodifacoum is so overwhelming that such a study or studies would probably be considered unfeasible by the registrant. Furthermore, it is misleading on our part to

6

suggest that such a study is a reasonable request when we recognize it's expected magnitude.

If the third option is chosen, we would retract our request that ICI conduct further field studies to determine population effects and would indicate to the Registration Division that Brodifacoum should be placed into special review.

The registrant, by regulation, still has the option to perform any studies they desire to try to show that their chemical is safe. We would continue to provide guidance if they chose that route. The difference is that we would not be requesting the studies.